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| 09/764,163 | 01/16/2001 | Robert F. Balint | PARE.002.02US | 7613 |

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| EXAMINER |
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PONNALURI, PADMASHRI

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| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,163

Applicant(s)

BALINT ET AL.

Examiner

Padmashri Ponnaluri

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80 and 84-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80, 84-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/05 has been entered.

2. Claims 81-83 have been canceled by the amendment filed on 7/21/05. Claims 1-79 were canceled and new claims 80-89 were added by the amendment filed on 8/29/03. Claim 89 were canceled by the amendment filed on 1/24/05.

3. Claims 80, 84-88 are currently pending and are being examined in this application.

Priority

4. This application claims priority to provisional application 60/175,968 and this application is a CIP of 09/526,106.

Specification

5. The specification has not checked to the extent necessary to determine the presence of all possible minor errors. Applicant's co-operation is requested in correcting any errors of which applicant may become aware in the specification.

Withdrawn Claim Rejections

6. The written description rejection set forth in the previous office action has been withdrawn in view of the amendments.

New Claim Rejections

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 80, 84-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 80 recites 'a polypeptide consisting essentially of', which is vague and indefinite.

It is not clear what does applicants mean by 'consisting essentially of', does applicants mean that the polypeptide has a first interactor domains covalently bonded to N-terminal and C-terminal break point of circularly permuted β -lactamase protein. It is not clear whether the claimed polypeptide has circularly permuted β -lactamase is linked to two interactor domains or the claim polypeptide has interactor domain and/or second interactor domain.

The instant claim is drawn to a 'polypeptide', which is considered as a single long (without breaks) amino acid sequence (peptide sequence). Thus, it is not clear what does applicants mean by 'consisting essentially of', does applicants mean that the polypeptide may have different peptides or sequences linked or the polypeptide has first and/or second interactor domains.

Generally 'consisting essentially of' is use for a 'composition' and/or 'method' claims (see MPEP 211.03), thus it is not clear what does applicants mean 'a polypeptide consisting essentially of'. Applicants are suggested to use clear phrases such as 'a polypeptide comprising' (open ended) or 'consisting of' (closed) to amend the claim.

b) Claim 84 recites the limitation "said enzyme" in line 3. There is insufficient antecedent basis for this limitation in the claim or in claim 80.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 80, 84-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 63-65 of copending Application No. 09/526,106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference application claims are drawn to 'a polypeptide consisting essentially of an N-terminal β -lactamase fragment, a flexible polypeptide linker and first interactor domain.' The reference does not recite that the polypeptide has a second interactor domain linked to the β -lactamase. However the reference flexible polypeptide

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linker refers to one of the interactor domain of the instant claims; and the β -lactamase fragment is same as the instant claim β -lactamase, because the amino acid sequence of instant claim β -lactamase before circularly permuted is same as the reference β -lactamase sequence; and further the reference claims intended use of the claimed oligopeptide in fragment complementation system which use the circularly permuted β -lactamase. And further the reference claims recite 'an polypeptide....consisting essentially of an N-terminal β -lactamase fragment....', the recitation of 'consisting essentially' makes the claim open and may include other peptides or fragments. Thus, the reference claim polypeptide is clearly same as the instant claim polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 80, 84-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 63-74 of copending Application No. 10/668,778. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims are drawn to a fragment complementation system comprising first oligopeptide comprising N-terminal fragment of a class β -lactamase covalently bonded to a first interactor domain; and a second oligopeptide comprising a C-terminal fragment of a β -lactamase protein covalently bonded to a second interactor domain, wherein upon binding of said interactor domain with said interactor domain, said N-terminal fragment and C-terminal fragment functionally reconstitute to form the β -lactamase protein (which refers to the instant claim polypeptide). The reference β -lactamase has same sequence as the instant claim β -lactamase protein sequence prior to circular permutation.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

12. Applicants arguments in response to the lack of written description rejection have been persuasive. The arguments are moot in view of the amendments and the rejection has been withdrawn.

13. Applicant's arguments filed on 7/21/05 regarding the rejection of claims under obvious type double patenting, have been fully considered but they are not persuasive.

Applicants have requested to hold the rejection until patentable subject matter has been found', which does not obviate the rejection. The rejection would be withdrawn upon filing and entering of terminal disclaimer to overcome the rejections.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PADMASHRI PONNALURI
PRIMARY EXAMINER

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

22 September 2005